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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,145	10/26/2007	Darren Michael CAINE	P-271-US1	4948
27038 7590 04/20/2010 THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 04/20/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,145	Applicant(s) CAINE, DARREN MICHAEL	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-26 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 is/are allowed.
- 6) ☒ Claim(s) 8-14 and 17-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3 sheets</u> . | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-14 AND 17-26 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed September 21, 2006 have been received and entered into the application.

Accordingly, the application has been amended as indicated. Further, as reflected by the attached, completed copy of form PTO-1449, (1 sheet), the cited references have been considered.

Specification

The specification is objected to because it fails to contain a section headed by "Brief Description of the Drawings".

Appropriate correction is required.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific disease states, does not reasonably provide enablement for treatment of all diseases/conditions or the prophylaxis of any disease/condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without and undue burden of experimentation.

***Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First
Paragraph***

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that all diseases/conditions may be treated or prevented is doubted the term “preventing” is synonymous with the term “curing” and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as diseases/conditions disclosed, e.g., claims in claims 25 and 26.

Also, in order to accept that a particular compound is effective for the prevention of any disease or condition one skilled in the art would have to be satisfied that a particular compound, or combination of compounds, could affect the pathoetiological factors associated with the disease or condition whereby the disease or condition could be kept from ever becoming manifest. This is here lacking in the present specification.

The Examiner further doubts that all diseases, or clinical conditions could be treated as

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claimed as such reads on a “panacea” which denotes that a compound is effective against all diseases/conditions. The art is simply unaware of any such compound, or combination of compounds, which could reach the objective. Data would be necessary to support such a claim.

Thus, because of the above reasons, the Examiner doubts the objective truth of the statement that the presently claimed active agent(s) can prevent/treat all clinical conditions/diseases, the Examiner has satisfied the burden as set forth in *In re Marzocchi, Id.* for making a rejection under 35 U.S.C. § 112, first paragraph.

The claims are therefore deemed properly rejected.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 and 17-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims set forth compounds not identified by structure, but merely by name which name does not have antecedent basis in the claims. Thus, the skilled artisan would not be aware of the metes and bounds of the subject matter for which Applicant seeks patent protection.

Appropriated correction is required.

Allowable Claims

Claims 1-7 are deemed allowable because the Examiner was unable to locate any relevant reference of record or in a search of the appropriate data bases which teach or would have suggested the claimed subject matter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
Art Unit 1614

April 19, 2010